JAC 1653 #

PTO/SB/64/(6-95)

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PATENT
Customer No. 22,852
Attorney Docket No. 3806-0488-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Christian VISKOV	)	Group Art Unit: 1653
	)	
Application No.: 09/742,008	)	Examiner: Kam, C.
	)	
Filed: December 22, 2000	)	
	)	
For: NOVEL PROCESS FOR PREPARING CYCLOSPORIN DERIVATIVES	)	

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 C.F.R. § 1.137(b)

The above-identified application became abandoned for failure to file a timely and proper response to the Office Action mailed on June 25, 2003. The abandonment date of this application was December 26, 2003 (i.e., the day after the expiration date of the period set for response plus any extensions of time obtained therefore). The Patent Office mailed a Notice of Abandonment March 12, 2004, following an Examiner Interview with Applicant's attorney of record, who confirmed that a response had not been filed to the June 25, 2003, Office Action.

The failure to file a timely response to the outstanding Office Action and the resultant abandonment of this application by the Applicant was unintentional. Applicant

has worked diligently to explain and correct the abandonment from the time they learned of the unintentional abandonment to the filing of this Petition and accompanying papers. Thus, the entire delay in filing the required reply, from the due date for the reply until the filing of this petition, was unintentional. Applicant presents the following facts in support of this statement.

Further to written instructions from the Applicant, which were believed to instruct Applicant's attorney of record to allow this application to go abandoned, the undersigned formally closed the application matter and informed the Applicant of such closure. Since no response was received from Applicant indicating this application to be maintained, when the June 25, 2003, Office Action was received, it was not acted upon, including not forwarded to the Applicant.

On March 12, 2004, the undersigned received from the Office a Notice of Abandonment. The Notice included an Interview Summary from an interview with the undersigned's supervisor on February 6, 2004, indicating the application had been abandoned. The Notice of Abandonment was forwarded to the Applicant, who promptly responded to the undersigned that the Applicant's files included no indication of any intention to abandon the application, nor any formal letter instructing such action. In response to the Applicant's correspondence of inquiry and concern, Applicant's attorney of record responded, identifying the relevant letter of general instruction relied upon. Shortly thereafter, the Applicant sent a letter clearly stating that there was a misunderstanding between the Applicant and the undersigned and that there was never any intention on behalf of the Applicant to abandon the application. Accordingly, the Applicant's abandonment was unintentional, as defined by 37 C.F.R. § 1.137(b).

Applicant hereby petitions for revival of this application since it was unintentionally abandoned. The petition fee as set forth in 37 C.F.R. § 1.17(m) of $1,330.00 is enclosed.

In addition, Applicant submits a response to the above-identified Office Action in the form of a Response to Restriction Requirement.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

If there are any other fees due in connection with the filing of this response, including any fees required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested, and the Commissioner is authorized to charge any related fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 17, 2004

By: 

Aaron M. Raphael
Reg. No. 47,885

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated June 25, 2003, the period for response to which is the subject of the concurrently filed Petition to Revive, the Examiner required restriction under 35 U.S.C. § 121 between the following groups:

> Group I (claims 1-14 and 22-23, drawn to a process for preparing a polyanion for use as an intermediate in the preparation of a cyclosporin derivative, comprising treating a cyclosporin with a hexamethyldisilazane metal salt; or a process for preparing a cyclosporin derivative substituted at 3-position, comprising preparing the polyanion);
>
> Group II (claims 15-16, drawn to a method for preventing or treating a retrovirus infection or an associated syndrome, comprising administering to a mammal a cyclosporin derivative defined in part 1-4 or 7 of claim 14);
>
> Group III (claims 17 and 19-20, drawn to a method for treating a chronic inflammatory disease, an autoimmune disease or inflammation, comprising administering to a

mammal a cyclosporin derivative in part 5-6 or 8 of claim 14);

Group IV (claim 18, drawn to a method for preventing or treating an autoimmune disease or preventing rejection of a transplant organ, comprising administering to a mammal a cyclosporin derivative in part 6 or 8 of claim 14); and

Group V (claim 21, drawn to a method for treating schistosomiasis, filariasis, leishmaniasis, coccidioidomycosis, or malaria, comprising administering to a mammal a cyclosporin derivative in part 6 or 8 of claim 14).

Applicant elects to prosecute Group I, claims 1-14 and 22-23, drawn to a process for preparing a polyanion for use as an intermediate in the preparation of a cyclosporin derivative, comprising treating a cyclosporin with a hexamethyldisilazane metal salt; or a process for preparing a cyclosporin derivative substituted at 3-position, comprising preparing the polyanion; with traverse.

In traversing the restriction requirement, Applicant directs the Examiner's attention to M.P.E.P. § 803, which sets forth criteria for the Examiner to follow in making a proper requirement for restriction. The following passage is pertinent to the issue herein.

CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent (see M.P.E.P. §§ 802.01, 806.04, 808.01) or distinct as claimed (see M.P.E.P. §§ 806.05-806.05(i)); and

(2) There must be a serious burden on the Examiner if restriction is not required (see M.P.E.P. §§ 803.02, 806.04(a)-(i), 808.01(a), and 808.02).

In the present case, the Examiner has not shown that there would be a serious burden involved in examining Groups I-V, despite the statement that the inventions are distinct. Applicant respectfully submits that a search of Groups I-V would not be burdensome, as all of the method of use claims recite using a compound represented by formula I. As the Examiner points out, all five groups are classified in class 514, among others. Accordingly, a proper search for the subject matter of one group would necessarily overlap the search for the subject matter of the remaining groups. Thus, a search for the subject matter cited in all groups would not be burdensome.

The Examiner also required that Applicant "select one cyclosporin compound from claim 4 or claim 14 (or claim 23) with each R1, R2, R4 to R11, and Z1, Z2 and Z4-Z11 defined." Applicant elects the compound of Example 1, [(R)-2-(N,N-dimethylamino)ethylthio-Sar]^3-[4'-hydroxy-MeLeu]^4-cyclosporin A. This corresponds to a compound of claim 4 wherein the substituents are as defined in group ii. That is, the radicals R_1, R_2, and R_4 to R_{11}, and Z_1, Z_2, and Z_4 to Z_{11} are defined as for cyclosporin A, with the exception of R_4 and Z_4, which are defined so as to have, at the 4-position, the amino acid 4'-hydroxy-methylleucine.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 17, 2004

By: _____
Aaron M. Raphael
Reg. No. 47,885